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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,828

03/22/2004

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EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

11/06/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/806,828	<b>Applicant(s)</b> ATLADOTTIR ET AL.	
	<b>Examiner</b> ELIZABETH HOUSTON	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15,38 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15,38 and 40-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/02/09, 05/05/09</u> .                                      | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 02/02/09 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. References that have not been considered are noted on the IDS 1449.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

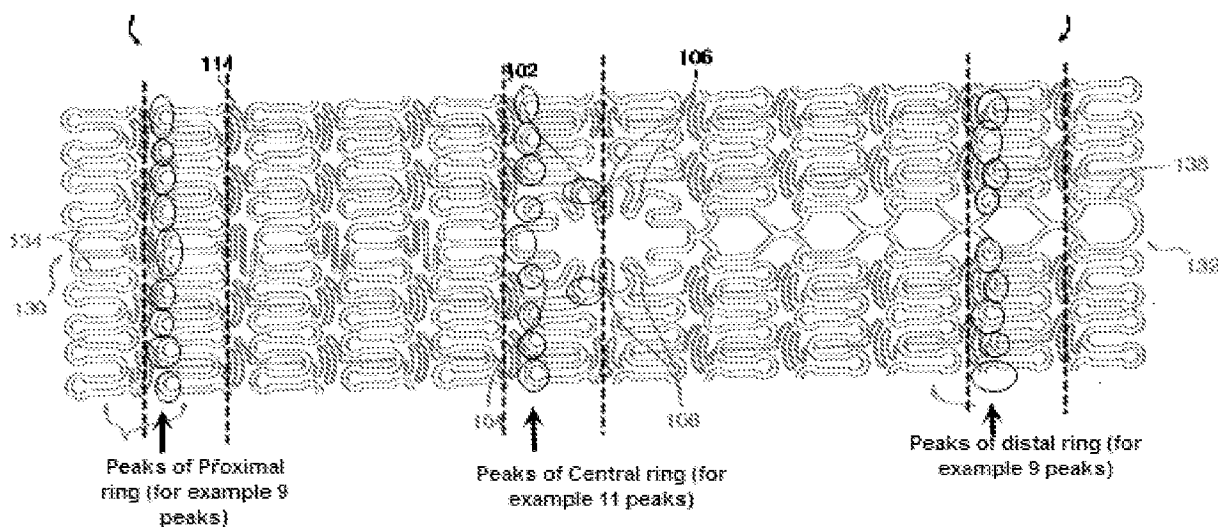
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Vardi (WO99/36002).

4. Vardi discloses a self-expanding stent (p12:1122-23) (Fig. 10) for treating a bifurcated vessel having a main vessel and a side branch vessel (see Fig. 1), comprising: a cylindrical body having a central longitudinal axis, wherein such cylindrical body is defined by a plurality of rings (for example 112, 122) spaced along such axis and wherein each ring is centered about such axis, adjacent rings being connected by links (114), and the cylindrical body having an unexpanded state and an expanded state; the cylindrical body having a proximal section (for example 110), a distal section

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(for example 120), and a central section (for example 102), each such section being defined by selected rings of said plurality of rings; a number of first peaks in each of the rings of the central section differing from a number of first peaks in each of the rings of the proximal section and the distal section(see below) to thereby provide additional material for apposing a side branch vessel; and the first peaks of the rings of the central section being configured to flare radially outwardly into an opening to the side branch vessel contacting the luminal wall of the side branch vessel and into at least a portion of the side branch vessel (for example Fig. 9); wherein the cylindrical body self-expands from the unexpanded state to the expanded state.



5. Claim 2: wherein the rings of the proximal section have between four and twelve first peaks, the rings of the distal section have between four and twelve first peaks, and the rings of the central section have between five and fifteen first peaks (see above).

Claim 3: wherein the rings of the proximal section have seven first peaks, the rings of the distal section have six first peaks, and the rings of the central section have eight first peaks (see above). Claim 4: the number of first peaks in the ring(s) of the central

section is greater than the number of first peaks in any of the rings in either the proximal section or the distal section (see above). Claim 5: the rings are connected by at least one links between adjacent rings (114). Claim 6: the tubular body has a distal opening (132), a proximal opening (130), and a central opening (102). Claim 7: the distal opening and the proximal opening are aligned along the stent longitudinal axis (see Fig. 10). Claim 8: the central opening is radially offset relative to the alignment of the distal opening and the proximal opening (see Fig. 10).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 9, 10, 15, 38, 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi (WO99/36002) in view of Roubin (US 5,827,321).

Vardi discloses the invention as stated above including claim 42: the body is formed of a single hypotube (p4:ll15-16), but does not disclose that the self expanding stent is formed of a self expanding alloy or superelastic material that is nitinol. Regarding claim 15: the central section will have a larger diameter than the proximal or distal ends since it expands outward radially. However, St. Germaine discloses that it is old and well known to use a shape memory superelastic metal alloy like nitinol to create a self-expanding stent. It would have been obvious to one having ordinary skill in the art at the

time of the invention to incorporate the claimed material into the stent since a person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results, namely a material that provides self-expanding capabilities.

8. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi in view of Roubin as applied to claim 1 and further in view of Guruwaiya (US 6,251,136).

9. Modified Vardi discloses the invention substantially as claimed except for the layer of drug and the primer material. Guruwaiya discloses a stent coated with a primer layer, which readily adheres to the material of the stent and is in turn constructed to retain a layer of pharmacological agent (Col 2: L20-34). Guruwaiya discloses that it is well known to be beneficial to deliver drugs with stents to treat problems such as thrombosis or neointimal hyperplasia. Guruwaiya further discloses using a primer layer of a polymer that more readily carries and releases the drugs as a benefit to layering the drug directly to the stent material. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a drug layer into the bifurcated stent since it is an old and well known enhancement to be able to treat the tissue with drugs while at the same time providing the treatment of the stent. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a primer layer between the stent layer and the drug layer since the primer layer will more

readily carry and release the drug that the stent material may not be able to carry and release.

### ***Response to Arguments***

10. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./  
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
11/05/09